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10/089,245	08/21/2002	Toshihiro Sadaoka	50069-11	4541
20277 7590 12/12/2008 MCDERMOTT WILL & EMERY LLP 600 13TH STREET, N.W.			EXAMINER	
			CHOL, FRANK I	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/089 245 SADAOKA ET AL. Office Action Summary Examiner Art Unit FRANK I. CHOI 1616 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment, See 37 CFR 1,704(b). Status Responsive to communication(s) filed on <u>03 September 2008</u>. 2b) This action is non-final. 2a) ✓ This action is FINAL. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-3 is/are pending in the application. Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-3 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers The specification is objected to by the Examiner. 10) The drawing(s) filed on 21 August 2002 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3.\times Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Pate. Notice of Draftsperson's Fatent Drawing Review (PTO 948)

Paper No(s)/Mail Date \_

Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)

6) Other:

Notice of Informal Patent Application (PTO-152)

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## DETAILED ACTION

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for selectively capable of absorbing oxidized sebum in preference to other types of sebum, does not reasonably provide enablement for selectively capable of absorbing oxidized sebum to the exclusion of other types of sebum. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The prior art is directed to a sebum absorbing paper containing hydroxyapatite which is selectively capable of absorbing oxidized sebum from other types of sebum.

The state of the prior art and the predictability or lack thereof in the art:

The prior art discloses papers containing hydroxyapatite and that hydroxyapatite can selectively absorb oxidized oils. However, the prior art does not disclose that hydroxyapatite can selectively absorb oxidized sebum to the exclusion of other types of sebum.

The amount of direction or guidance present and the presence or absence of working examples:

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The Specification discloses an experiment in which pseudo sebum, i.e. oleic acid, oleic oxide and olive oil, were tested, however, there was no showing that hydroxyapatite did not absorb at least some non-oxidized oil.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they encompass absorbing of oxidized sebum from other types of sebum, i.e. to the exclusion of other types of sebum. As such, one of ordinary skill in the art would be required to do undue experimentation in order to show that the hydroxyapatite containing paper did not absorb to any extent other types of sebum.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

Contrary to the Applicant's arguments the phrase "selectively capable of absorbing oxidized sebum from other types of sebum" does encompass the exclusion of other types of sebum. The mere fact that the Applicant does not intend the same does not overcome the rejection. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As such, the Applicant cannot argue that the Specification limits the limitation to only encompass a preference of oxidized sebum over other types of sebum.

Contrary to the Applicant's arguments, the Examiner has considered the WANDS factors as indicated above. See Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213, 18 USPQ2d 1016 (Fed. Cir. 1991) (stating that the Wands factors "are illustrative, not mandatory" and that what is relevant to an enablement determination depends upon the facts of the particular case).

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordnary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 393 723 in view of the acknowledged prior art, JP 11-137336, US Pat. Fujii et al. (US Pat. 5,041,252), JP 63188628 and JP 63027411.

EP 0 393 723 discloses papers and nonwoven fabrics carrying or incorporating calcium phosphate compounds in the form of powders, granules or porous granules, having a particle size of 0.1 to 30 microns (Pg. 6, lines 7-15). It is disclosed that the paper contains 10 to 80% by weight of the calcium phosphate compound as a filler (Pg. 8, lines 43,44). It is disclosed that hydroxyapatite is a suitable calcium phosphate compound (Pg. 8, lines 44,45). It is disclosed that the calcium phosphate compound is generally solely used as a filler in the functional paper, however, if desired, it may be used together with conventions fillers such as talc (Pg. 9, lines 8-10). It is disclosed that preferably the functional paper shows a basis weight of 20 g/m² or more (Pg. 9, line 40). It is disclosed that the functional paper can be used to adsorb any oil-soluble substances which could not be adsorbed with an activated carbon (Pg. 4, line 58, Pg. 5, line 1). It is disclosed that the functional paper can be used in diapers, sanitary nakins and pads for bedsores (Pg. 9, lines 45-50).

The Applicant acknowledges that the skin surface, in particular around the nose and chin and middle of the forehead, tends to be oil due to the frequent secretion of sebum. It is disclosed

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that the human skin is damaged by oxidized sebum generated by its exposure to the air while the time passes after its secretion. (Specification, Page 1).

Fujii et al. disclose nonwoven fabric in the form of baby's napkin, women's sanitary napkin and toilet paper, which is not stimulative to the skin and has soft and good touch feeling, applied to the skin, in which inorganic materials, such as apatite and the like are added to improve the properties of the nonwoven fabric (Column 3, lines 9-16, Column 4, lines 52-67). It is disclosed that the nonwoven fabric can have a basis weight of 5 to 500 g/m², preferably 5 to 400 g/m², more preferably 10 to 300 g/m². (Column 4, lines 14-20).

JP 11-137336 discloses a paper used to absorb sebum from the skin containing talc having an average particle size of 1.2 microns where the basic weight of the paper is in the range of 15-25 g/m2 (Paragraphs 0048, 0023).

JP 63027411 disclose that hydroxyapatite is effective in eliminating skin lipid byproducts that have an adverse effect on the skin and that hydroxy apatite powder demonstrates excellent selective absorption of peroxidized lipids (See Page 3 of translation of 63027411).

JP 63188628 disclose that lipid peroxides produced by oxidative deterioration cause rough skin and acne inflammation and that hydroxyapatite absorbs these sebaceous waste products (See Page 6 for translation of 63188628).

EP 0 393 723 discloses papers and non-functional papers containing calcium phosphate and talc which is used to absorb oils. The difference between EP 0 393 723 and the claimed invention is that the prior art does not expressly disclose a sebum absorbing paper used for applying to skin or for cleaning skin which contains 1-30% by weight hydroxyapatite and has a basis weight of 5 to 25 g/m<sup>2</sup> which is selectively capable of absorbing oxidized sebum from other

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types of sebum. However, the prior art amply suggests the same as it is known in the art to use papers containing hydroxyapatite and talc as absorbants (See JP 11-137336, JP 63027411 and JP 63188628), papers having a basis weight of 15-25 g/m2 containing talc are known to be used for absorbing sebum/oil from the skin (See JP 11-137336) and that hydroxyapatite is used in cosmetic products to selectively absorb oxidized lipids (See JP 63188628). As such, one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that a paper having a basis weight of 15-25 g/m2 containing hydroxyapatite and talc would be suitable for selectively absorbing oxidized sebum from the skin because hydroxyapatite powders are known to be effective in selectively absorbing oxidized lipids from the skin and papers having a basis weight of 15-25 g/m2 are disclosed as suitable for use in absorbing sebum and oil from the skin

The Examiner had duly considered Applicant's arguments but deems them unpersuasive for the reasons of record and the further reasons below.

Also, the Supreme Court in KSR International Co. v. Teleflex Inc., held the following:

- (1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;
- (2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

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(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art

can provide a reason for combining the elements in the manner claimed;

- (4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problemcommon sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);
- (5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396, 1397 (U.S. 2007). Contrary to the Applicant's arguments, the Examiner has applied the above paragraphs to the present case as indicated below.

The Applicant refers to various easelaw discussing motivation. However, motivation is no longer a require element of a prima facie case of obviousness. Further, In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). As

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such, there is no requirement that EP'723 disclose that the paper is capable of selectively absorbing oxidized sebum; that JP'336 disclose the use of hydroxyapatite, that Fujii et al. disclose the absorption of sebum, that JP'411 disclose the use of paper or selectively absorbing oxidized sebum from other types of sebum; that JP'628 disclose the use of paper.

The prior art, as indicated above, discloses a paper having a basis weight of 15-25 g/m2 which is suitable for absorbing sebum on the skin. As such, it would have been well within the skill of and one of ordinary skill in the art would expect that EP '723 papers having said basis weight would also be suitable for absorbing sebum on the skin. The mere fact that EP'723 does not explicitly teach that the paper can be used to absorb sebum on skin does not overcome the rejection. As indicated above, it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes and one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle. Further, the fact that EP'723 discloses examples in which the basis weight is greater than 25 g/m2 does not overcome the rejection. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

The Applicant argues that the Examiner has failed to explain why one of ordinary skill in the art would reasonably expect that that a product taught as directly applied to skin or used in other delivery systems with the notable exception of paper could be applied to the skin with paper. However, the prior art, as indicated above, disclose that powders can be incorporated into papers for application to the skin for absorbing seburn. JP'628 and JP'411 disclose that the

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hydroxyapatite is in the form of a powder and absorbs oxidized sebum. EP'723 discloses the incorporation of powdered hydroxyapatite into paper. As such, there is amply reason for one of ordinary skill in the art to expect that the hydroxyapatite powders of JP'628 and JP'411 can be incorporated into paper. As indicated above, one of ordinary skill in the art is not an automaton.

Contrary to the Applicant's arguments, the prior art, as indicated above, does disclose that hydroxyapatite can selectively absorb oxidized sebum. JP'628 discloses that hydroxyapatite powder adsorbs sebaceous waste products that cause rough skin and acne inflammation, i.e. various lipid peroxides produced by oxidative deterioration (Page 6 of the translation of JP'628). In any case, the limitation "selectively capable of absorb oxidized sebum from other types of sebum" requires no manipulation than what is already suggested by the prior art, i.e. the addition of hydroxyapatite to paper to absorbed oxidized sebum. "The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985) (The prior art taught combustion fluid analyzers which used labyrinth heaters to maintain the samples at a uniform temperature.

Although appellant showed an unexpectedly shorter response time was obtained when a labyrinth heater was employed, the Board held this advantage would flow naturally from following the suggestion of the prior art.).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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## Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am –4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (tol-free).

Frank Choi Patent Examiner Technology Center 1600 December 13, 2008

/Johann R. Richter/ Supervisory Patent Examiner, Art Unit 1616